Development of a core outcome set for use in interventions aimed at improving appropriate polypharmacy in older people in primary care

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Intervention studies seeking to improve appropriate polypharmacy (≥4 medicines) in older people (≥65 years) often differ in reported outcomes, making it challenging to synthesise results.[1] To address this, the Core Outcome Measures for Effectiveness Trials (COMET) initiative has proposed the development of a core outcome set (COS).[2] A COS is an agreed, standardised outcome set which should be measured and reported, as a minimum, in all trials in a specific clinical area. The COMET initiative also recommends involving public participants in COS development, facilitating a move away from researcher-only selected outcomes.[2]

This study aimed to develop a COS for use in effectiveness trials of interventions aiming to improve appropriate polypharmacy in older people in primary care.

Standard COS development methodology was followed, comprising: (1) an update of an existing Cochrane systematic review[1]; (2) identification of outcomes from previously collected qualitative data, and; (3) an online, three-round, Delphi consensus exercise. An international expert panel (n=120) and a public participant panel (n=40) were recruited for the Delphi exercise. Expert panellists included those with knowledge relevant to the COS (e.g. general practitioners, pharmacists, researchers). Public panellists included older people who were resident in the community. Identified outcomes were scored on a 9-point Likert scale using the GRADE scoring system anchored between 1 (not important) and 9 (critical). Consensus criteria for outcome inclusion were defined as ≥70% of participants scoring the outcome as 'critical' and ≤15% scoring the outcome as 'not important'. The seven highest ranked outcomes were also identified in line with COMET recommendations.[2] The study was approved by the School of Pharmacy Ethics Committee, Queen's University Belfast.

Twenty-nine outcomes identified from updating the Cochrane review and existing qualitative data were included in the Delphi exercise. After three Delphi rounds, which were completed by 152, 140 and 127

participants respectively, the final COS comprised 16 outcomes, with priority given to the seven highest ranking outcomes: 'serious adverse drug reactions', 'medication appropriateness', 'falls', 'medication regimen complexity', 'quality of life', 'mortality' and 'medication side-effects'. The remaining nine outcomes were: 'hospitalisations', 'patient's knowledge', 'adherence', 'clinically significant drug interactions', 'number of regular medicines prescribed', 'therapeutic duplication', 'prescribing errors', 'cognitive functioning' and 'patient perception of treatment (or medication) burden'.

This work has identified 16 outcomes, which should be considered for inclusion in effectiveness studies aimed at improving appropriate polypharmacy in older people in primary care. We recognise that having many outcomes may be impractical. Therefore, in line with COMET recommendations, we have highlighted the seven highest ranking outcomes. We suggest that these seven outcomes should be priority outcomes, with the remainder considered depending on the specific intervention and theoretical underpinning. The value of public participants' involvement was evidenced in the final Delphi round whereby the outcome 'patient's knowledge' would not have been included if the panel only comprised experts. Implementation of this COS may benefit patients and healthcare providers by facilitating evidence synthesis. Future work should determine the most appropriate methods of measuring each included outcome.

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1. Patterson SM, Cadogan CA, Kerse N et al. Interventions to improve the appropriate use of polypharmacy for older people. Cochrane Database Syst Rev 2014; 10: CD008165.
2. Williamson PR, Altman DG, Bagley H et al. The COMET Handbook: version 1.0. Trials 2017; 18(3): 280.